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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,210	02/09/2001	Monica M. Jablonski	6704-11	6997

7590 10/07/2003

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,210	JABLONSKI ET AL.	
	Examiner	Art Unit	
	Zohreh Fay	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-17 are presented for examination.

The amendments and remarks filed on July 21, 2003 have been received and entered.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of certain disorders caused by damage, disruption, or degeneration of RPE cells or a Muller cell, does not reasonably provide enablement for the broad phrase of inhibiting the generative condition of photoreceptor cell in a retina caused damage, disruption, or the degeneration of RPE cells or a Muller cell" using brimonidine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant.

The factors to be considered determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are

(1) The nature of the invention,

(2) The state of the prior art;

(3) The relative skilled of those in the art,

(4) The predictability or unpredictability of the art,

(5) The breadth of the claims,

(6) The amount of direction or guidance presented,

(7) The presence or absence of working examples, and

(8) The quantity of experimentation necessary.

When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The claims are drawn to a method of inhibiting, treating, delaying or reversing a degenerative condition of a photoreceptor cell in a retina, which disease or condition is caused by damage, disruption, or the degeneration of an RPE cell or a Muller cell, using brimonidine.

(2) The state of the art:

According to Wen et al. each the use of the claimed compound, brimonidine for the treatment of certain retinal diseases, such as retinitis pigmentosa or age related macular degeneration. The state of the art does not recognize the use of brimonidine in the treatment of unspecified disorders coverd under the general term of degenerative disorders caued by damge to certain cells as easily done.

(3) The relative skilled of those in the:

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art;

The unpredictability of pharmaceutical, chemical and neurodegenerative art is high.

(5) The breadth of the claims:

The clams are very broad and encompass treatment or inhibition of a degenerative condition of a photoreceptor cell in the retina, which is caused by damage disruption or degeneration of an RPE cell or a Muller cell.

(6) The amount of direction or guidance presented:

Applicant's specification provides guidance and it is only enabled for the treatment and prevention of certain disorders caused by damage, disruption or degeneration of an RPE cell or a Muller cell. However the specification provides no guidance, to enable one skilled in the art to use the invention commensurate with claims.

(7) The presence or absence of working examples

The examples in the specification describe treating certain disorders caused by the degeneration, damage or disruption of RPE cells or Muller cells, but fail to enable the skilled in the art to use brimonidine in treating or inhibiting all disorders caused by the above reasons.

(8) The quantity of experimentation necessary

Applicant fails to provide guidance and information sufficient to allow skilled artisan to ascertain how to "inhibit" a degenerative condition of a photoreceptor cell in the retina. Absent such guidance and information, one skilled in the art would have to blindly experiment, with no reasonable a prior expectation of success being present. To determine the conditions necessary to achieve such an exceptional level of success would by definition require extensive and undue experimentation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Wen et al. (U.S. patent 6,066,675). Wen et al. Teach the use of the claimed compound, brimonidine in a pharmaceutical formulation for the treatment of the claimed disorders. See Claim 15, page 6 last paragraph and page 7 first paragraph.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (703) 308-4604. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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October 3, 2003

ZOHREH A. FAY
PRIMARY EXAMINER
GROUP 1200